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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/910,703	07/20/2001	Bruce J. Barclay	VASC 1020-2	2083

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EXAMINER	
PELLEGRINO, BRIAN E	

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 05/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

SP

Office Action Summary	Application No.	Applicant(s)	
	09/910,703	BARCLAY ET AL.	
	Examiner	Art Unit	
	Brian E Pellegrino	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 December 2004* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3,4,8,9,11,19-23,25,26,38-42,74-78,102,104 and 108* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3,4,8,9,11,19-23,25,26,38-42,74-78,102,104 and 108* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4/1/05* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 3,4,9,11,23,25,26,38-40,42,74-76,78,108 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khosravi et al. (5824054) in view of Khosravi et al. (5824053) and Herzog et al. (WO 98/08482). Khosravi et al. disclose a prosthesis with a coiled body **11** with a coiled sleeve **12** extending along the coiled body. Fig. 2 shows the coiled body has radially extending openings **14** therethrough. Khosravi also discloses the sleeve material is made of PTFE, col. 5, lines 9,10.The coiled body can be made of metal, col. 5, lines 55-60. Khosravi additionally discloses the sleeve material sandwiching the coiled body is porous, and substantially impervious to blood, col. 4, lines 63-67 and col. 5, lines 1-6,15-17. Khosravi does disclose a bioactive agent or drug can be included in the graft material, col. 4, line 65. Fig. 8A shows a stent body with a helical fashion and Khosravi also discloses various forms or modifications can be made to the body design, col. 10, lines 56-62. However, Khosravi et al. fail to disclose the body follows a general helical path and that the drug used to be a NO generator or that a delay release material is used to control release of the drug, i.e. encapsulation. Khosravi '053 shows (Fig. 1) a stent body with a helical winding and this design provides high radial strength uniformly along the body, col. 5, lines 19-30. Herzog et al. teach a stent with a sleeve or coating having an interior surface that houses the stent, and a NO generator within the sleeve interior, page 6, lines 7,8, page 14, lines 20-32.

Herzog teaches the agent can also be encapsulated, page 12, line 11. Herzog et al. also teach that a delay-release material is used to control the release of the agent into the blood vessel, page 11, lines 26,27. It would have been obvious to one of ordinary skill in the art to modify the stent body design and use a helical form for strength as taught by Khosravi '053 and to substitute the drug and use a NO generator as taught by Herzog with the stent of Khosravi to inhibit restenosis.

Claims 3,4,8,9,11,23,25,26,38-42,74-78,108 are rejected under 35 U.S.C. 103(a) as being obvious over Fogarty (6585760) in view of Herzog et al. (WO 98/08482).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2). Fogarty discloses the

invention as claimed but fails to disclose the agent NO within the graft material or sleeve. Herzog is explained supra. It would have been obvious to one of ordinary skill in the art to modify the stent graft and incorporate a therapeutic agent as NO as taught by Herzog with the stent graft of Fogarty to inhibit restenosis.

Claims 8,41,77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khosravi et al. '054 in view of Khosravi et al. '053 and Herzog et al. (WO 98/08482) as applied to claim 38 above, and further in view of Kropf '849. Khosravi in view of Herzog is explained supra. However, Khosravi as modified by Herzog fail to disclose the coiled body having spaced apart turns having gaps and the body having longitudinal side members and cross members. Kropf teaches a coiled stent with spaced apart turns and longitudinal members connected with cross members, Fig. 5. Kropf teaches that the structural design enables the prosthesis to be deployed in a small profile reducing the likelihood of vessel trauma, col. 3, lines 8-13. It would have been obvious to one of ordinary skill in the art to substitute the stent design of Kropf in the stent of Khosravi as modified by Khosravi et al. '053 and Herzog et al. in order to provide a stent with good flexibility and a small profile for delivery.

Claims 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khosravi et al. '054 in view of Khosravi et al. '053 and Herzog et al. (WO 98/08482) as applied to claims 38 and 74 respectively above, and further in view Ragheb et al. (5873904). Khosravi in view of Herzog is explained supra. However, Khosravi as modified by Herzog fail to disclose the use of multiple agents with the sleeve. Ragheb teaches that porous polymers are used for controlling drug release, col. 6, lines 56-60.

Ragheb also teaches the use of first and second dispensable agents, col. 5, lines 58,59,63 and col. 6, lines 3-14. It would have been obvious to one of ordinary skill in the art to use a second agent as taught by Ragheb with the stent of Khosravi as modified by Khosravi et al. '053 and Herzog, such that the device has enhanced capabilities and multiple treatment capabilities. Regarding claim 22, it would have been an obvious matter of design choice to modify the ability of the stent to release at least half of a first agent before a second is released, since applicant has not disclosed that using any set amount of one over another provides any advantage, or solves a stated problem, or is used for any particular purpose. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the rates and amounts taught by Ragheb or the claimed at least half of first agent in claim(s) 22 because both designs perform the same function of releasing agents into the patient.

Claims 102,104 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khosravi et al. '054 in view of Khosravi et al. '053 and Herzog et al. (WO 98/08482) as applied to claims 38 and 74 respectively above, and further in view of Hanson (5399352). Khosravi in view of Herzog is explained supra. However, Khosravi as modified by Herzog fail to disclose the sleeve interior being oversized relative to the coiled body. Hanson teaches that a reservoir (oversized) is used alone to hold drugs, such as NO generators to prevent restenosis in combination with a prosthetic device, col. 5, lines 60-62, col. 6, lines 3-5. Hanson also shows (Fig. 4) the reservoir is oversized **20** for the drug. It would have been obvious to one of ordinary skill in the art to use an oversized reservoir as taught by Hanson within the sleeve interior holding the

stent of Khosravi as modified by Khosravi et al. '053 and Herzog so that a sufficient or greater amount of drug can be administered to the site.

Response to Arguments

Applicant's arguments filed 12/2/04 have been fully considered but they are not persuasive. Applicant contends the prior art Khosravi and Herzog do not disclose a *sleeve*, but fails to acknowledge that the examiner is not relying on Herzog for the *sleeve* since Khosravi already discloses an outer layer or sleeve. According to Microsoft reference the definition of a *sleeve* is: a casing that holds an object. A claim term used contrary to its ordinary meaning, must be clearly redefined in the written description to set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). Since the outer material of Khosravi clearly surrounds the inner stent it can be construed as a *sleeve*.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Pellegrino whose telephone number is (571) 272-4756. The examiner can normally be reached on Monday-Thursday from 6:30am to 4pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

TC 3700, AU 3738

BRIAN E. PELLEGRINO
PRIMARY EXAMINER

Brian E Pellegrino